

A. Pulse Characterization

[0042] As described above, once the flow of a site has been characterized, the determination of whether the pulse of such a site is relatively or substantially high or low will further enable characterization of the type of sample obtainable from the site. For example, if a site is characterized as having high flow, a high pulse characterization correlates to a substantially arterial/capillary site and a low pulse characterization correlates to a substantially venous site, a relatively lower or substantially no pulse site correlates to an interstitial fluid site.

[0043] In certain embodiments, pulse can be determined by determining the RBC characteristics of a site, e.g., RBC flux, as described above. The methods for determining RBC characteristics such as RBC flux have been described above and will not be repeated here. Once the RBC flux is determined, further characterizing pulsations (from the RBC flux) corresponding to cardiac pulse indicates whether the site is arterial or venous, based on the principle that an arterial/capillary site will have a greater pulse than a venous site. Cardiac pulsations are observed as oscillations with a frequency of typically between 60 and 100 pulses per minute in the RBC flux vs. time relationship, as described above (it will be apparent to one of skill in the art that certain clinical conditions may result in higher or lower frequencies). The pulsations result from flow surges in arteries and capillaries. Because of the resistance to flow of the capillaries, flow pulsations do not occur in veins. More specifically, if pulsations ranging from about 0.33 to about 3.3 Hz, usually from about 0.67 to 2.50 Hz and more usually from about 0.85 to 1.67 Hz are characterized at the site, the site is characterized as arterial. Alternatively, if pulsation in this frequency range is not detected or is very weak, the site is characterized as venous, where pulsations less than the arterial/capillary pulsation levels indicates a site devoid or substantially devoid of vasculature. Thus, if a site is determined to have a high RBC flux (high flow) and is also highly pulsatile, the site is characterized as arterial/capillary, i.e., high flow and arterial/capillary, rather than venous. If the RBC flux is determined to have low or substantially no pulsatile flow, the site may either be devoid of vasculature or may be venous, i.e., an interstitial fluid site or a high flow and venous site.

B. Hemoglobin Characterization

[0044] In other methods of the present invention, sample type characterization is determined by characterizing the hemoglobin character of the site, for example a characterization of the total hemoglobin of the site will enable a determination of whether the site is capable of expressing arterial/capillary or venous sample or interstitial fluid, based on the principle that a site having substantially interstitial fluid will have little or no hemoglobin. Also, as an arterial/capillary site will have a greater amount of HbO than a venous site, characterizing a site's HbO/Hb ratio will enable a determination of whether the site is capable of expressing substantially arterial/capillary sample or substantially venous sample.

[0045] Accordingly, methods to measure optical properties of the potential site are used to determine the hemoglobin characterization of the potential site. In other words, the absorbance, e.g., the light reflected from, or transmitted through, the potential site is detected and measured, *i.e.*, an external portion of skin is irradiated with light (where light in this context does not necessarily refer to visible light, but may also include infrared light, *etc.*), and the absorbance of the light is detected, where such absorptions are indicative of hemoglobin characteristics of the site. In certain embodiments of the subject methods, the measured value is compared to a predetermined value to characterize the site. In other embodiments, it is compared to other hemoglobin values of other tested sites.

[0046] As described above, a site is irradiated with light and the light absorbed by the site, or rather the light reflected by or transmitted through the area of interest, is detected, where such detecting involves collecting the reflected or transmitted light or a statistically relevant value thereof, for example by at least one light detector of an optics element, and processing the detected data to determine the hemoglobin character of the site. For example, the detected light or a respective signal may be transferred to a microprocessor for further processing, where the microprocessor works under the control of a software program. In other words, the program code in the software program instructs the microprocessor to carry out all the steps necessary to accomplish the particular task. Regardless of whether performed manually or automatically, the amount, magnitude or quantity of the reflected or transmitted light or a signal or relevant statistical value thereof may be compared to a predetermined value. For example, if the signal were to be above a predetermined value, the site might be determined to have a

high total hemoglobin level or high HbO/Hb ratio. Alternatively, if the signal were to fall below a predetermined value, the site might be determined to have a substantially low hemoglobin level or low HbO/Hb ratio. Alternatively, or in addition to, the above method employing a predetermined value to which the measured value is compared, in those instances where the best available site is sought, i.e., the most appropriate site in relation to other sites tested, the measured value or statistically relevant value thereof may be compared to measured values of other tested sites. Typically, this optical irradiation and detection takes about 0.1 to 180 seconds and more usually about 0.1 to 60 seconds, and more typically about 0.1 to 20 seconds.

[0047] Thus, in practice, light from at least one light source, *i.e.*, an optics element, *e.g.*, at least one LED, laser emitting diode, light emitter, bispectral emitter, dual spectral emitter, photoemitter, photodiode, a semiconductor die or the like at a wavelength in the range from about 400 to 1200 nm, irradiates the site, where in some embodiments more than one wavelength is used from the same or different light sources, where the different wavelengths may irradiate the site at the same or different times. Usually, the site will be irradiated for about 0.1 to 180 seconds, typically about 0.1 to 60 seconds and more typically about 0.1 to 20 seconds and then the absorbed light will be detected by a suitable detector such as at least one of the following: a photodiode, a photoelectric receiver, a photodetector, a semiconductor die, or the like. The detected signal is then related to hemoglobin concentration, *i.e.*, total hemoglobin or a component or suitable ratio thereof. In certain embodiments, the detected light is then communicated to a suitable microprocessor for further processing such as computational processing and the like.

[0048] By way of background, generally when the skin is illuminated by light, if the light were to enter the skin, reflect off the collagen at the bottom of the dermis and re-emerge from the skin without absorption by an chromophores, (*e.g.*, melanin or hemoglobin), the signal (remittance) detected and thus generated by the photodetector could be defined as R_c . When chromophores in the epidermis (melanin) and the dermis (hemoglobin) intervene, the reflectance is attenuated, giving a signal defined as R_{tot} . Thus, an equation representative of the signal received is defined as:

$$[0049] \quad (1) \quad R_{tot} = T_m^2 \cdot T_{HbO}^2 \cdot T_{Hb}^2 \cdot R_c$$